



[Billing Code 4140-01-P]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

A Strategic Roadmap for Establishing New Approaches to Evaluate the Safety of Chemicals and Medical Products in the United States; Availability of Report

AGENCY: National Institutes of Health, (HHS).

ACTION: Notice.

SUMMARY: The Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM) coordinated the development of a strategic roadmap for establishing new approaches to evaluate the safety of chemicals and medical products in the United States. This document, prepared with support from the National Toxicology Program Interagency Center for the Evaluation of Alternative Toxicological Methods (NICEATM), is now available.

ADDRESSES: The report is available at <https://ntp.niehs.nih.gov/go/natl-strategy>.

FOR FURTHER INFORMATION CONTACT: Dr. Warren Casey, Director, NICEATM; email: warren.casey@nih.gov; telephone: (984) 287-3118.

SUPPLEMENTARY INFORMATION:

Background: Scientific and technological advances in toxicology can significantly improve and protect public health. However, a national strategy is required to ensure the safe, effective, and timely implementation of human-based, predictive approaches in toxicity testing.

The goal of the U.S. Strategic Roadmap is to realize the vision set forth in the

seminal National Research Council report “Toxicity Testing in the 21st Century: A Vision and a Strategy.” This 2007 report envisioned using human-based assays and model information to provide a more efficient, predictive, and economic system for assessing the effects of chemicals on human health.

The U.S. Strategic Roadmap was developed with participation from the 16 ICCVAM member agencies and multiple interagency workgroups, as well as input from a broad range of stakeholder groups. It describes a new framework that will enable development, establish confidence in, and ensure use of new approaches to toxicity testing that improve human health relevance and reduce or eliminate the need for testing in animals.

Summary of Report Contents: The successful development and implementation of new approaches to toxicity testing will require coordinated efforts that address three strategic goals:

- Connect end users with developers of new approach methodologies
- Foster the use of efficient, flexible, and robust practices to establish confidence in new methods
- Encourage the adoption and use of new methods and approaches by federal agencies and regulated industries

Implementation of the roadmap goals, already underway in specific testing areas, will include key elements needed for advancement of alternative methods.

Availability of Report: The report is available at <https://ntp.niehs.nih.gov/go/natl-strategy>.

Background Information on ICCVAM and NICEATM: ICCVAM is an interagency

committee composed of representatives from 16 federal regulatory and research agencies that require, use, generate, or disseminate toxicological and safety testing information. ICCVAM conducts technical evaluations of new, revised, and alternative safety testing methods and integrated testing strategies with regulatory applicability and promotes the scientific validation and regulatory acceptance of testing methods that more accurately assess the safety and hazards of chemicals and products and replace, reduce, or refine (enhance animal well-being and lessen or avoid pain and distress) animal use.

The ICCVAM Authorization Act of 2000 (42 U.S.C. 285l-3) establishes ICCVAM as a permanent interagency committee of the National Institute of Environmental Health Sciences and provides the authority for ICCVAM involvement in activities relevant to the development of alternative test methods. ICCVAM acts to ensure that new and revised test methods are validated to meet the needs of federal agencies, increase the efficiency and effectiveness and federal agency test method review, and optimize utilization of scientific expertise outside the federal government. Additional information about ICCVAM can be found at <http://ntp.niehs.nih.gov/go/iccvam>.

NICEATM administers ICCVAM, provides scientific and operational support for ICCVAM-related activities, and conducts and publishes analyses and evaluations of data from new, revised, and alternative testing approaches. NICEATM and ICCVAM work collaboratively to evaluate new and improved testing approaches applicable to the needs of U.S. federal agencies. NICEATM and ICCVAM welcome the public nomination of new, revised, and alternative testing approaches for validation studies and technical evaluations. Additional information about NICEATM can be found at

<http://ntp.niehs.nih.gov/go/niceatm>.

Dated: February 9, 2018.

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[FR Doc. 2018-03476 Filed: 2/20/2018 8:45 am; Publication Date: 2/21/2018]